Dechert LLP

502 Carnegie Center
Suite #104
Princeton, NJ 08540-7814
+1 609 955 3200 Main
+1 609 955 3259 Fax
www.dechert.com

ROBERT D. RHOAD

robert.rhoad@dechert.com
+1 609 955 3269 Direct
+1 609 873 9142 Fax

September 25, 2019

VIA ECF

Honorable Douglas E. Arpert
United States Magistrate Judge
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *Par Pharmaceutical, Inc. et al. v. Sandoz Inc.*, 3:18-cv-14895-BRM-DEA (District of New Jersey)

Dear Judge Arpert:

This firm represents the Plaintiffs (collectively "Par") in the above-captioned litigation. We write in opposition to the letter submitted on September 19th by Defendant Sandoz Inc. ("Sandoz") regarding its motion to compel Par to affirmatively disclaim its reliance on objective indicia of non-obviousness while discovery is still ongoing (or preclude its reliance on the same) and to produce all documents that have been produced in antitrust and trade secret litigations involving Par. For the reasons set forth herein, Sandoz's motion should be denied.

Background

With respect to Sandoz's first issue, relating to Par's contentions with respect to any objective indicia of non-obviousness, on May 29, 2019, Par served its 215-page Responses to Sandoz's Invalidity Contentions as required by Local Pat. Rule. 3.4A ("Par's Validity Contentions") setting forth its contentions in response to the invalidity arguments raised by Sandoz. Days later, on June 3, 2019, Par timely served its responses to Sandoz's First Set of Interrogatories, including Interrogatory No. 4 about which Sandoz now complains. In its response to Interrogatory No. 4, Par objected that the request was premature but, despite this, Par included a substantive response that clearly stated "Par responds that at this time, it has not identified any secondary considerations of non-obviousness on which it currently intends to rely." Sandoz Ltr. at Ex. B. On

September 25th, Par amended its response to Interrogatory No. 4 to incorporate its Validity Contentions that were served on May 29th. To date, Par has produced nearly 250,000 pages of discovery, including prior art asserted in other litigations and invalidity contention discovery from other vasopressin litigations. Fact discovery is currently set to close on January 31, 2020.[1] Dkt. No. 19.

Over a month ago, Sandoz complained that Par should identify any secondary considerations of non-obviousness now, or be precluded from relying on them. Ex. 1.[2] Par responded that it currently does not intend to raise secondary considerations of non-obviousness, but could not agree at this early stage to foreclose the possibility that such evidence could be uncovered during discovery. Sandoz Ltr. at Ex. C. If that were to happen, Par would seek leave to amend its response to Sandoz's invalidity contentions in accordance with L. Pat. R. 3.7. Par heard nothing further on this topic and considered the matter resolved. Par has represented that it will not rely on commercial success (Sandoz Ltr. at Ex. C) and now represents that it will not rely on long-felt need.

The other issue raised by Sandoz is its request that Par produce ***all*** of the documents Par has produced in antitrust and trade secret litigations involving Par, without regard to whether the documents produced have any relation to any disputed

---

[1] To that end, Sandoz failed to meet and confer with Par as required by Rule 37.1. In support of its motion, Sandoz attaches an August 6, 2019 letter from Par which summarizes Par's positions on Sandoz's discovery complaints. But, Sandoz did not attach its August 13th email response, which stated that while it "disagree[d] with the discussion of the ESI search terms in [Par's letter], [it] appreciate[d] [Par's] compromise offer" and accepted Par's offer to produce additional documents if Sandoz agreed that it would seek no additional search terms. Ex. 1. Sandoz took no other issues with Par's position on the remaining topics in the August 6th letter, leaving Par to believe that Sandoz had accepted Par's objections and would not pursue the issues any further. Sandoz's September 19th letter was a surprise to Par because Sandoz's recent email implied that it took no issues with Par's response.

[2] References to numbered "Ex. __" herein refer to the corresponding exhibits attached to the Declaration of Robert D. Rhoad. Lettered exhibits refer to exhibits to Sandoz's September 19, 2019 letter.

issue in this case or would otherwise be discoverable in this action. Sandoz has served 104 document requests seeking numerous categories of documents relevant to disputed issues in this case. Par has responded to those requests, and searched for and produced nearly 250,000 pages of documents. Sandoz now seeks ***all*** documents produced in antitrust and trade secret litigations, even though the majority of those documents undoubtedly relate to the many issues in those litigations that have no overlap with any disputed issues in this case and would not be discoverable in this case. Par is not withholding any document from production in this case on the grounds that it was produced in another case; rather, Par is objecting to wholesale production in this case of all documents produced in other litigations without regard to their relevance to this one.

Sandoz's Request to Foreclose Par's Reliance on Secondary Considerations Is Unripe, Premature and Would Be Prejudicial to Par

Under Fed. R. Civ. P. 26(e)(1) a party must supplement or correct a discovery response "***if*** the party learns that in some material respect the disclosure or response is incomplete or incorrect, ***and if*** the additional or corrective information has not otherwise been made known to the other parties" (emphasis added). Where a party fails to do so, under Fed. R. Civ. P. 37(c)(1), "the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." In determining whether to grant the "extreme" sanction of excluding evidence, courts consider a number of factors, including the prejudice to the parties, the ability to cure the prejudice, the extent to which the evidence would disrupt the orderly and efficient trial, and any bad faith or willfulness in failing to comply with a court order or discovery obligation. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 07-cv-3770-DMC, 2010 WL 1849913, at *4 (D.N.J. May 7, 2010) (citations omitted). Courts regularly deny requests for sanctions precluding evidence because no harm or prejudice has been shown, even when disclosures happen at late stages in the litigation. *See Reckitt Benckiser Inc., Tris Pharma, Inc.*, No. 09-cv-3125-FLW, 2011 WL 4962221, at *8-9 (D.N.J. Oct. 18, 2011) (denying motion to preclude use of secondary considerations disclosed a week before fact discovery closed); *see also Eli Lilly*, 2010 WL 1849913, at *1 (granting request to allow testimony where witness was first disclosed days before trial).

Sandoz's request to preclude Par from relying on evidence of objective indicia is unripe, meritless and, if granted, would be prejudicial to Par. Sandoz has not (and

cannot) identify any harm that it has suffered because the behavior Sandoz complains about—that Par may identify new secondary considerations of non-obviousness—is merely hypothetical. Sandoz's unjustified speculation of "eleventh hour" disclosures and disclosures "in expert reports" should be disregarded. *See* Sandoz Ltr. at 1, 4. None of that has happened. The "eleventh hour" of the fact discovery deadline is still months away, with fact discovery set to close on January 31, 2020, and the expert discovery deadline is even further, closing on June 5, 2020. Dkt. No. 19; *see also Tech. Licensing Corp. v. Technicolor USA, Inc.*, No. CIV. 2:03-1329 WBS EFB, 2010 WL 4292275, at *2-3 (E.D. Cal. Oct. 26, 2010) (finding that an exclusion order was premature where discovery was ongoing). Moreover, Sandoz's complaints are overstated. For example, it argues in its letter that additional discovery will be needed were Par to rely on commercial success and long-felt need. Sandoz Ltr. at 1. Yet, on the very next page, Sandoz cites a letter in which Par already confirmed that it "will not assert commercial success as a secondary consideration." *Id.* at 2. Furthermore, Par hereby confirms that it does not intend to rely on the secondary consideration of long-felt but unmet need. Sandoz has also made no argument that denying its motion would have any impact on the "orderly and efficient trial" in this case. *See Eli Lilly*, 2010 WL 1849913, at *4. Indeed, *Markman* proceedings are just beginning and dates for pretrial conference and trial have not yet been set.[3] Dkt. No. 19.

Par Would Be Prejudiced by the Exclusion

Par has diligently provided discovery, giving Sandoz its best information, based on its current investigation, as to the objective indicia upon which it intends to rely. Par provided its validity contentions responsive to Sandoz's invalidity contentions, and Par has supplemented its Response to Interrogatory No. 4 on September 25th to incorporate

[3] Sandoz cites *King Pharms., Inc. v. Sandoz Inc.*, No 08-cv-5974 (GEB), 2010 WL 2015258, at *5 (D.N.J. May 20, 2010) to argue that it would be too late for Par to now rely on secondary considerations of validity. But, the facts in *King Pharms.* are very different from here, where that Court denied a motion to amend invalidity contentions because Defendant had not been diligent in seeking an amendment and an amendment would have inevitably delayed the trial date. *Id.*

its validity contentions.[4] Given the posture of this case, Par would be prejudiced from a forced commitment to either identify or forever foreclose reliance on objective indicia of non-obviousness. Courts have found prejudice to the non-moving party in circumstances even far less favorable. This Court in *Reckitt Benckiser*, for example, found that Plaintiff would be prejudiced if its evidence of secondary considerations were excluded where Plaintiff disclosed four new secondary considerations a week before fact discovery closed. 2011 WL 4962221, at *2, 8. The Court found that Plaintiff may have been responsible for the delayed supplement: however, without a showing of willfulness, bad faith, or a history of dilatoriness, sanctions were not warranted. *Id*. at *8. "[P]recluding the secondary considerations asserted by Plaintiffs . . . would result in more substantial prejudice accruing to Plaintiffs by preventing a complete adjudication of this matter on the merits." *Id.* The potential prejudice to Par, and lack of prejudice to Sandoz, is even more compelling here than in *Reckitt Benckiser*, because Par and Sandoz still have many months to conduct additional discovery.

Sandoz's Cited Cases are Inapposite

None of the cases supplied by Sandoz support its arguments. Only one case even discusses the exclusion sanction that Sandoz seeks here—*Boehringer Ingleheim Pharma GmbH & Co KG v. Teva Pharms. USA, Inc.*, No. 14-7811, Dkt. No. 319 (D.N.J. Oct. 18, 2017)—and the rest are inapposite.[5] The facts in *Boehringer*, however, are readily

[4] Any claim that Par is trying to hide the ball falls flat. In its validity contentions, Par included citations to the prosecution histories and patent specification, specifically including citations to the examples and figures therein that correspond to the data and information referenced in the office action cited by Sandoz in its letter. *Compare, e.g.*, Sandoz Ltr., Ex. D (office action citing data and information in accompanying Kannan declaration), *with* Ex. 2 (Kannan declaration cited therein), Ex. 3 (excerpt of validity contentions citing '526 patent at Examples 9, 10 and Figs. 11-18), *and* Ex. 4 (cited examples and figures in '526 patent). Sandoz has been aware of Par's contentions in that regard for months.

[5] Sandoz's reliance on *RawCar Grp., LLC v. Grace Med., Inc.*, No. 13-cv-1105-H, Dkt. No. 107 (S.D. Cal. June 6, 2014) and *Eurand, Inc. v. Mylan Pharms., Inc.*, 263 F.R.D. 136 (D. Del. 2009), is misplaced. In both cases, Plaintiff had expressed an intention to rely on one or more objective indicia of non-obviousness but refused further discovery

distinguishable. There, the court excluded claim construction positions that Defendants had willfully declined to raise until after claim construction had completely finished. *Id.* at 12. Here, discovery is ongoing and no deadline has passed such that Sandoz would be prejudiced without excluding evidence, as was the case in *Boehringer*.

Sandoz's Motion to Compel Production from Unrelated Litigations is Meritless

Sandoz's sole basis for demanding that Par now produce ***all*** of the documents produced in the *QuVa* trade secret case and the *Fresenius* antitrust case is that there is some overlap in issues between those cases and this one. The mere existence of any such overlap, however, does not justify Sandoz's request for wholesale production of every document from those other litigations.

With respect to *QuVa*, Sandoz asserts that there is overlap because Par alleges that the "specific diluent" for its formulation is a trade secret, and some of the dependent claims recite the use of a diluent. This infringement case, however, is about Sandoz's ANDA product and whether it infringes Par's patent, not about Par's product or whether the "specific diluent" used with it is or is not a trade secret. Sandoz fails to explain how an allegation that a "specific diluent" is a trade secret has any bearing on any disputed issue of infringement or validity in this case. Sandoz cites case law purportedly holding that one cannot claim both trade secret and patent protection for the same subject matter, but that proposition has no bearing in this case. Whether Par has disclosed trade secrets in a patent, thereby giving up the secrecy required for trade secret protection, is not relevant to whether Sandoz infringes Par's patent. Equally importantly, Sandoz does not allege that Par's existing production is in any way deficient with the respect to the diluent limitation recited in any asserted claim of the patents-in-suit.

The issues in *Fresenius*, relating to alleged anticompetitive conduct, is even further removed from the issues in this case. Sandoz's only argument for why Par's *Fresenius* production is relevant is an alleged connection to commercial success and long-felt need as secondary considerations of non-obviousness. Sandoz Ltr. at 5. But, as

---

relating to it. *Rawcar*, at 9-10 (noting that Plaintiff identified several categories of secondary characteristics); *Eurand*, at 138, 141 (requiring only that Plaintiff supplement responses regarding evidence "on which they presently rely").

noted above, Par has affirmatively committed that it does not intend to raise either of those issues.

Accordingly, there is no basis to compel wholesale production of the documents Par produced in either the *QuVa* or the *Fresenius* litigations. *See Eisai Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-cv-4168-MLC, 2011 WL 5416334, at *8 (D.N.J. Nov. 7, 2011) (refusing to grant motion to compel production from different litigation involving different parties, different contractual structures, and a different product); *see also Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-cv-571-MLC, 2016 WL 6089699, at *4 (D.N.J. Oct. 14, 2016) (affirming decision to deny motion to compel production of prior litigation documents involving the same accused product). Indeed, in the *Noven* case on which Sandoz relies, although the Court ordered production of specified documents from another litigation whose relevance to the suit at issue was undisputed, it denied the wholesale production of all "Remaining Documents" from that other litigation. *Noven Therapeutics, LLC v. Prinston Pharm. Inc.*, No. 14-cv-7400, Dkt. No. 97, slip op. at 5 (D.N.J. July 19, 2016) (discussing production of copies of the proceedings from a related litigation and finding that having common specification was insufficient to support the motion to compel of the remaining documents).

Sandoz's assertion that the burden on Par of wholesale production of documents from other litigations would be minimal is misguided and wrong. Par has already diligently provided discovery to Sandoz in this matter, to-date producing nearly 250,000 pages of documents, many relating to development of Vasostrict®. Par has also produced documents from other litigations, including prior art and invalidity contention discovery involving the patents-in-suit. Par cannot simply duplicate for Sandoz its productions in the *Fresenius* and *QuVa* litigations, without review, as argued by Sandoz. Sandoz Ltr. at 5. At minimum, Par must review every single document for relevance and confidentiality under the two-tier framework in this case (*see* Dkt. No. 34) and incur costs associated with data processing and storage. Moreover, wholesale production would needlessly expose Par's highly confidential information on numerous issues entirely irrelevant to this matter to people who have no need or reason to have it. There is no justification for doing so. This is the classic "fishing expedition."

Sandoz misinterprets its cited cases as "ordering production of documents produced in related litigation." Sandoz Ltr. at 5. None of Sandoz's cited cases ordered a party to duplicate its production from another case. *Noven* involved particular records

from another litigation proceeding (such as deposition transcripts and witness statements) whose relevance to the suit at issue was not in dispute, and *Dexcel* involved specified documents that formed the basis of the infringement positions in other litigation (such as test methods). *See Noven*, No. 14-cv-7400, Dkt. No. 97, slip op. at 3; *Dexcel Pharma Techs. Ltd. v. Takeda Pharm. Co. Ltd.*, No. 16-cv-4957, Dkt. No. 61, slip op. at 1-2 (D.N.J. Nov. 16, 2016). Neither case ordered a party to duplicate its productions from other litigations.

Conclusion

For all of the foregoing reasons, the Court should deny Sandoz's motion to compel Par to affirmatively disclaim its reliance on objective indicia of non-obviousness while discovery is still ongoing (or preclude its reliance on the same) and to produce wholesale all documents produced in other litigations.

Respectfully submitted,

/s/ Robert D. Rhoad

Robert D. Rhoad

cc: All Counsel of Record (via ECF and e-mail)